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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/731,499	10/16/1996	JOE W. GRAY	2500.124US1	6686

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QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/731,499

Applicant(s)

GRAY ET AL.

Examiner

Karen A Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1.6-19,23 and 45-69 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1.6-19,23 and 45-69 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11/14/03.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claim 69 has been amended. Claims 1, 6-19, 23 and 45-69 are pending and under consideration.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

3. The rejection of claim 69 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in light of applicants amendments.

4. The rejection of claims 1, 6, 8, 10, 12, 14, 16, 18, 45, 46, 47-61, 63, 64, 68 and 69 under 35 U.S.C. 102(b) as being anticipated by Tanner et al (Cancer Research, 1994, Vol. 54, pp. 4257-4260, reference A3 of the IDS filed April 15, 1997) is maintained.

Claim 1 is drawn to an isolated nucleic acid molecule comprising a labeled polynucleotide sequence that hybridizes under stringent conditions to a sequence or a complement of a sequence selected from the group consisting of SEQ ID NO:2, 3, 4, 5, 6, 7, 8, 9, and 10. Claims 6, 8, 10, 12, 14, 16 and 18 embody the isolated nucleic acid of claim 1 wherein said polynucleotide hybridizes to a complement of SEQ ID NO:4, 5, 6, 7, 8, 9 and 10, respectively. Claim 45 embodies the isolated nucleic acid of claim 1 wherein said nucleic acid has a length greater than about 50 nucleotides. Claim 46 specifies that the isolated nucleic acid molecule is a DNA molecule. Claim 47 is drawn to an isolated nucleic acid molecule comprising a promoter operably linked to a polynucleotide sequence selected from the group consisting of SEQ ID NO:2, 3, 4, 5, 6, 7, 8, 9, 10 and 12. Claims 48-57 embody the isolated nucleic acid of claim 47 wherein the promoter is operably linked to SEQ ID NO:2, 3, 4, 5, 6, 7, 8, 9, 10 and 12, respectively. Claim 58 is drawn to an isolated nucleic acid molecule comprising a polynucleotide sequence that hybridizes under stringent conditions to a sequence or a complement of a sequence selected from the group consisting of SEQ ID NO:2, 3 and 12. Claims 59-61 embody the nucleic acid sequence of claim 59 wherein the polynucleotide

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sequence hybridizes under stringent conditions to a complement of SEQ ID NO:2, 3, and 12, respectively. Claim 63 embodies the isolated nucleic acid sequence of claim 58 wherein the nucleic acid is labeled. Claim 64 is drawn to an isolated nucleic acid sequence comprising SEQ ID NO:9, 10 or 12. Claim 68 embodies the isolated nucleic acid of claim 1 wherein the labeled polynucleotide comprises a radioactive label, a fluorescent label, an electron dense reagent, a colorimetric label, or a magnetic label. Claim 69 embodies the isolated nucleic acid of claim 1, wherein the labeled polynucleotide comprises a biotin-moiety, a dioxigenin moiety, a hapten or an antigenic peptide.

Tanner et al disclose the cosmid probe RMC20C001 labeled with biotin which hybridized to the q13 region of chromosome 20. Tanner et al disclose that after hybridization the probe was detected by avidin-fluorescein isothiocyanate, thus fulfilling the specific embodiment of claim 68 with respect to a fluorescent label and claim 69 with respect to biotin. Tanner et al disclose that this cosmid defined the region of highest copy number in primary breast tumors (page 4259, under the heading Analysis of Primary Breast Cancers). The instant specification states on page 3, lines 20-21, that SEQ ID NO:1-10 and 12 are nucleic acid sequences within the 20q13 amplicon. Thus, SEQ ID NO:2-10 and 12 would be comprised within the 20q13 amplicon and the cosmid would hybridize under stringent conditions to said amplicon.

Applicant argues that the RMC20C001 cosmid shares no overlapping sequence with the ZABC1 and thus, the disclosure of the RMC20C0)1 cosmid does not anticipate the instant claims. However, it is noted that claim 1 does not exclude isolated nucleic which comprise rather than consist of SEQ ID NO:2-10 or the complements of SEQ ID NO:2-10. Because SEQ ID NO:2-10 and 12 are comprised within the 20q13 amplicon, and the RMC20C001 hybridizes to said amplicon, the disclosure of Tanner et al anticipates the instant claims.

5. The rejection of claims 58-61 under 35 U.S.C. 102(b) as being anticipated by The New England Biolabs Catalog (1993-1994, page 91, cited in a previous Office action) is maintained for reasons of record. Applicant argues that the examiner has not provided any alignments of the random hexamers or calculations of hybridization efficiency and has therefore failed to make a prima facie case. This has been considered but not found persuasive. It is well known in the

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art that random hexamers are a collection of random 6-mer oligos and that statistical analysis indicates that a 6-mer cannot represent a unique sequence in a library of expressed or genomic polynucleotides. Indeed Lathe (J Mol Biol, 1985, Vol. 183, No. 1, pp. 1-12) teaches a minimum lengths of 16-18 nucleotides to define a unique fragment within a collection of expressed sequences from a single mammalian organism and a minimum length of 18-20 nucleotides to define a unique fragment within a single mammalian genome (see for instance page 10, Table 6). Thus, one of skill in the art would know that polynucleotide sequences of the length of SEQ ID NO:2-10 would comprise a sequence to which one or more of the random hexamers would hybridize. Thus, providing an alignment between a single random hexamer and the instant nucleic acid molecules would not be necessary. Regarding the lack of hybridization efficiencies in the examiners rejection, it is noted that the claims do not have limitations regarding hybridization efficiencies. Thus, any amount of a random hexamer that were to remain hybridized on SEQ ID NO:2-10 or a complement of SEQ ID NO:2-10 under the conditions of the claims (0.02 molar salt and a temperature of at least 60 degrees) would fulfill the specific embodiments of the claim, irrespective of hybridization efficiencies.

6. The rejection of claims 1, 6-19, 23 and 45-67 under the judicially created doctrine of obviousness-type double patenting over claims 11-17 of USP 5,801,021 is maintained until the time that applicants file a terminal disclaimer.

7. The rejection of claims 1, 6-13, 23, 45-53, 58-60 and 63 under the judicially created doctrine of obviousness-type double patenting over claims 1-9 of USP 5,892,010 is maintained. The rejection is maintained until the time that applicants file a terminal disclaimer.

8. All other rejections and objections as set forth in the previous Office action are withdrawn.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308 8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A

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message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308 3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 0196.

A handwritten signature in cursive script, reading "Karen A. Canella", followed by a horizontal flourish line.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

01/02/04